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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**JAZZ PHARMACEUTICALS, INC. and  
JAZZ PHARMACEUTICALS IRELAND  
LIMITED,**

**Plaintiffs,**

**v.**

**WOCKHARDT BIO AG, WOCKHARDT  
LIMITED, and WOCKHARDT USA LLC,**

**Defendants.**

**Civil Action No. \_\_\_\_\_**

**COMPLAINT FOR  
PATENT INFRINGEMENT**

**(Filed Electronically)**

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, “Jazz Pharmaceuticals”), by their undersigned attorneys, for their Complaint against defendants Wockhardt Bio AG, Wockhardt Limited, and Wockhardt USA LLC (collectively, “Wockhardt”), allege as follows:

**Nature of the Action**

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Wockhardt’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market a generic version of Jazz Pharmaceuticals’ XYREM<sup>®</sup> drug

product prior to the expiration of United States Patent No. 9,050,302 (the “’302 patent” or “the patent-in-suit”) owned by Jazz Pharmaceuticals.

**The Parties**

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

3. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at One Burlington Road, Fourth Floor, Connaught House, Dublin, Ireland 4.

4. On information and belief, defendant Wockhardt Limited is an Indian corporation having a principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East) Mumbai – 400 051, Maharashtra, India. On information and belief, Wockhardt Limited is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Wockhardt Limited regularly conducts business in New Jersey, including in this Judicial District.

5. On information and belief, defendant Wockhardt Bio AG is a Swiss corporation, having a principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. On information and belief, Wockhardt Bio AG is a wholly-owned subsidiary of Wockhardt Limited. On information and belief, Wockhardt Bio AG is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Wockhardt Bio AG regularly conducts business in New Jersey, including in this Judicial District.

6. On information and belief, defendant Wockhardt USA LLC is a company organized and existing under the laws of the State of Delaware, with its principal place of

business at 20 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054-1271. On information and belief, Wockhardt USA LLC is a wholly-owned subsidiary of Wockhardt Limited. On information and belief, Wockhardt USA LLC is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, and Wockhardt USA LLC regularly conducts business in New Jersey, including in this Judicial District.

7. On information and belief, Defendants Wockhardt USA LLC, Wockhardt Limited, and Wockhardt Bio AG acted collaboratively in the preparation and submission of ANDA No. 207526 to the FDA. On information and belief, Wockhardt Bio AG's submission of ANDA No. 207526 to the FDA was done at the direction, under the control, and for the direct benefit of Wockhardt Limited.

8. On information and belief, following any FDA approval of ANDA No. 207526, Defendants Wockhardt USA LLC, Wockhardt Limited, and Wockhardt Bio AG will work in concert with one another to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 207526 throughout the United States, and/or import such generic products into the United States.

### **Jurisdiction and Venue**

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Defendant Wockhardt USA LLC because, *inter alia*, Wockhardt USA LLC's principal place of business is located in the State of New Jersey. Wockhardt USA LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

11. This Court has personal jurisdiction over Defendant Wockhardt Limited because, *inter alia*, Wockhardt Limited has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. On information and belief, Defendant Wockhardt Limited regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its affiliates, including Wockhardt USA LLC. On information and belief, Wockhardt Limited derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey. Wockhardt Limited has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction

12. This Court has personal jurisdiction over Defendant Wockhardt Bio AG because, *inter alia*, Wockhardt Bio AG has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. On information and belief, Defendant Wockhardt Bio AG regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its affiliates, including Wockhardt USA LLC. On information and belief, Wockhardt Bio AG derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey. Wockhardt Bio AG has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**The Patent-In-Suit**

14. On June 9, 2015, the United States Patent and Trademark Office duly and lawfully issued the '302 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '302 patent is attached hereto as Exhibit A.

**The XYREM<sup>®</sup> Drug Product**

15. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM<sup>®</sup>. The claims of the patent-in-suit cover, *inter alia*, methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patent-in-suit.

16. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '302 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM<sup>®</sup>.

17. The labeling for XYREM<sup>®</sup> instructs and encourages physicians, other healthcare workers, and patients to administer XYREM<sup>®</sup> according to the methods claimed in the patent-in-suit.

**Acts Giving Rise to This Suit**

18. Pursuant to Section 505 of the FFDCA, Wockhardt filed ANDA No. 207526 ("Wockhardt's ANDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Wockhardt's Proposed Product"), before the patent-in-suit expires.

19. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Wockhardt has provided a written certification to the FDA, as called

for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Wockhardt’s Paragraph IV Certification”), alleging that the claims of the ’302 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt’s ANDA.

20. No earlier than November 26, 2015, Jazz Pharmaceuticals received written notice of Wockhardt’s Paragraph IV Certification (“Wockhardt’s Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B). Wockhardt’s Notice Letter alleged that the claims of the ’302 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt’s ANDA. Wockhardt’s Notice Letter also informed Jazz Pharmaceuticals that Wockhardt seeks approval to market Wockhardt’s Proposed Product before the patent-in-suit expires.

21. On information and belief, Wockhardt has not submitted a statement to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Wockhardt seeks to market its Proposed Product for a use other than the uses claimed in the patent-in-suit.

22. Under applicable laws and regulations, the FDA will not approve Wockhardt’s Proposed Product with labeling that does not include information regarding dose modification in patients receiving concomitant administration of sodium oxybate and valproate that is necessary for the safe and effective use of sodium oxybate.

**Count for Infringement of the ’302 Patent**

23. Jazz Pharmaceuticals repeats and realleges the allegations of paragraphs 1-22 as though fully set forth herein.

24. Wockhardt’s submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the ’302 patent, constitutes infringement of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

25. There is a justiciable controversy between the parties hereto as to the infringement of the '302 patent.

26. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the claims of the '302 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Wockhardt's Proposed Product in the United States.

27. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the claims of the '302 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '302 patent and knowledge that its acts are encouraging infringement.

28. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the claims of the '302 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '302 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

29. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '302 patent is not enjoined.

30. Jazz Pharmaceuticals does not have an adequate remedy at law.

31. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Jazz Pharmaceuticals respectfully requests the following relief:

- (A) A Judgment be entered that Wockhardt has infringed the patent-in-suit by submitting ANDA No. 207526;
- (B) A Judgment be entered that Wockhardt has infringed, and that Wockhardt's making, using, offering to sell, selling, or importing Wockhardt's Proposed Product will infringe one or more claims of the patent-in-suit;
- (C) An Order be entered that the effective date of FDA approval of ANDA No. 207526 be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;
- (D) Preliminary and permanent injunctions be issued enjoining Wockhardt and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Wockhardt's Proposed Product until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;
- (E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Wockhardt, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patent-in-suit, or from actively inducing or contributing to the infringement of any claim of the patent-in-suit, until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;
- (F) A Declaration be issued that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Wockhardt's Proposed Product will directly infringe, induce and/or contribute to infringement of the patent-in-suit;



(G) To the extent that Wockhardt has committed any acts with respect to the compositions and methods claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Jazz Pharmaceuticals be awarded damages for such acts;

(H) If Wockhardt engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Wockhardt's Proposed Product prior to the expiration of the patent-in-suit, a Judgment awarding damages to Jazz Pharmaceuticals resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: January 7, 2016

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

I hereby certify that the matters captioned, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al.*, Civil Action No. 13-391 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-1360 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 15-3217 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-3684 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, Civil Action No. 15-4532 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Wockhardt Bio AG, et al.*, Civil Action No. 15-5619 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Lupin Ltd., et al.*, Civil Action No. 15-6548 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 15-6562 (ES)(JAD), and *Jazz Pharmaceuticals, Inc., et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 15-7580 (ES)(JAD) are related to the matter in controversy because they involve defendants who filed Abbreviated New Drug Applications seeking to market generic versions of the same drug product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: January 7, 2016

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